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BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/508,635
Filing Date: May 18, 2000
Appellant(s): BALLEVRE ET AL.

Robert Barrett
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the reply brief filed 7/10/06.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this ground of rejection, appellants have characterized the Examiner's argument as amounting to the following:

> "Because a couple of additional methods of internally administering are not specifically disclosed in the specification, [the examiner argues that] there is insufficient support for the phrase 'internally administering' ".

However, this was not the basis of the rejection. The examiner makes no argument that there is a *per se* requirement that all possible forms of internal administration must be listed in order for there to be descriptive support for the term "internally administering". In fact, if the phrase in question had been recited in the specification, there would be no need to recite even one specific example of internal administration.

The reply brief also states that the phrase "oral nutritional forms" can be found in the specification; however, appellants have not pointed to any specific location in the text where this phrase might be found. Appellants have also argued that the specification recites "enteral administration" of the milk protein hydrolysate to which the claims are drawn; again, no specific location in the text is suggested. The examiner would note, however, that on page 9, line 6+, there is passing mention of a continuous

administration of a formula by means of enteral tubes, but this is not the same as an affirmative recitation of "enteral administration" in general, or "enteral administration" of the milk protein hydrolysate to which the claims are drawn. In any case, recitation of a continuous administration of a formula by means of an enteral tube does not provide descriptive support for "internally administering".

Next, appellants have argued that the artisan of ordinary skill would have had the skill to internally administer a formulation. In response, it may be true that the the artisan of ordinary skill would have had the skill to internally administer a formulation if given the suggestion to do so. In fact, there are numerous variations of the claimed invention that would be within the skill of e.g., a specialist in internal medicine, if given the suggestion to pursue such a course of action. But the issue is whether, in the absence of a suggestion to carry out a given process or procedure, the artisan of ordinary skill would recognize that the instant specification encompasses that process or procedure which was never suggested. In the instant case, there is no description of "internally administering".

As for the lack of descriptive support for recitation of an "internal" organ (claim 30), appellants have argued that they have "agreed" to delete this term. However, an "agreement" requires the consent of both parties; the examiner has not agreed to enter an amendment deleting this term, as it would potentially raise new issues, and require a new search. Accordingly, the merits of the rejections should be decided on the basis of the claims at issue, rather than on the basis of some other set of claims.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have argued that organ "recovery" can be quantified or defined by measuring protein concentration, RNA concentration, protein synthesis, or ribosomal efficacy.

In reponse, the examiner would agree that the skilled physiologist could measure protein synthesis or RNA concentration, but this does not amount to a showing of organ "recovery". As asserted by the specification (page 8, line 20+), the milk protein hydrolyzates can be used to treat Crohn's disease, sepsis and diarrhea. The fact that protein synthesis may be increased does not mean that the symptoms of these disorders have been ameliorated.

With respect to Crohn's disease, sepsis and diarrhea, appellants have argued that the claims do not specifically recite these disorders. This particular observation by appellants is correct. But it is also true that the phrase "promoting recovery of … [an] organ" encompasses treatment of the foregoing disorders, and so it is entirely appropriate to pursue an inquiry as to whether enabling support exists for such treatment.

Next, appellants have stated the following:

> "…the present claims recite, in part, a method of organ recovery as measured by the rate of protein synthesis (e.g. hydrolysis) using milk protein hydrolyzates, which the Examiner admits is enabled.

First, the claims are not drawn to "a method of organ recovery as measured by the rate of protein synthesis". Second, the examiner has never "admitted" that a method of organ recovery using milk protein hydrolyzates might be enabled; rather he has consistently argued that enablement is lacking.

Finally (page 4, reply brief), appellants have jumped to the conclusion that treatment of Crohn's disease, sepsis or diarrhea is a "beneficial effect" of administering the disclosed milk protein hydrolyzates. However, no reason is given as to why the skilled artisan would believe this to be true, and none is evident.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Appellants have suggested in effect that protein synthesis might equate with "organ recovery", or that RNA concentration can be equated with organ recovery. However, protein synthesis occurs whether or not an organ has been subject to physical trauma or disease. The fact that protein synthesis may be occurring does not mean that "organ recovery" is occurring, given that the term "organ recovery" encompasses treatment of Crohn's disease, diarrhea and sepsis. In the appeal brief filed 3/7/06, appellants argued (page 15) that the term "organ recovery" excludes treatment of hepatitis, cirrhosis and kidney infection. In the reply brief filed 7/10/06, appellants have argued that efficacy in the treatment of hepatitis, cirrhosis and kidney infection has "not been determined".

However, the basis of this rejection is not that of enablement *per se*, but rather what is encompassed by the term at issue ("recovery of an organ"). It remains unclear why appellants would argue that "recovery of an organ" encompasses treatment of Crohn's disease, diarrhea and sepsis, but at the same time, "recovery of an organ" excludes treatment of hepatitis, cirrhosis and kidney infection. More generally, it is unclear as to what disorders and biochemical processes are included or excluded by the term at issue.

✧

Claims 30, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Nakamura (*J. Dairy Sci.* **78 (**6) 1253-1257, 1995) in view of Ichikawa (USP 5,071,867) or Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996) in view of Ichikawa ('867) .

Appellants have argued that the milk protein hydrolyzates of Nakamura and of Masuda will not increase the rate of protein synthesis in an animal to which they are administered. However, the claims are not drawn to a method of increasing the rate of protein synthesis. What is required is that the milk protein hydrolyzate which is administered have the property of increasing protein synthesis under certain conditions. The biochemist of ordinary skill would expect that protein synthesis will be greater in an animal which has been administered (or fed) a protein source, at least relative to an animal who has had no protein intake for a considerable period of time. The instant claims do not specify any particular rate of protein synthesis, only that the rate of synthesis be increased relative to a reference point which the practitioner of the invention

might wish to choose. Thus, for example, the biochemist of ordinary skill would expect that a rat which had been administered the milk protein hydrolyzate of Nakamura or of Masuda will exhibit greater net protein synthesis than would a rat which had not had access to a protein source for several days.

Thus, by "selecting" the protein hydrolyzate of Nakamura or of Masuda, one is selecting a protein hydrolyzate which meets the requirements of the instant claims.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132).

Appellants have acknowledged that Gordon teaches (e.g., col 6, line 36) that milk protein hydrolyzates can be used to treat vascular tumors or arthritis. Appellants have argued, however, that tumors and arthritis **can** be treated topically, and because they **can** be treated topically, the skilled artisan would conclude that the milk protein hydrolyzates **cannot** be administered either internally or systemically. However, the dermatologist of ordinary skill, for example, would recognize that administration need not be limited to the surface of the skin. Moreover, any agent which is effective to treat arthritis is going to have to make its way well below the surface of the skin, at least to a point in the body which would qualify as "internal". In addition, Gordon recites (col 2, line 62) a general "pharmaceutical use"; the medical practitioner of ordinary skill would take this as an indication that other forms of administration will be effective. In addition, as stated (col

3, line 3+), "Further, … even when applied topically, the … healing effect … extends to areas below the surface of the skin…". The phrase "even when applied topically", together with the term "pharmaceutical use" suggests forms of administration beyond those that would reach just the surface of the skin.

Thus, the artisan of ordinary skill would recognize at least one form of administration that would qualify as "internal" administration.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132) in view of Verma (USP 6,645,942).

Appellants have traversed by arguing that Gordon taken by itself is deficient, and that Verma does not remedy the deficiency of Gordon. However as indicated above, Gordon is not deficient, and renders obvious the claimed invention. It therefore follows that Gordon in view of Verma constitutes a valid rejection as well.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Smith (WO 97/16460).

Appellants have suggested that the examiner has "admitted" that Smith does not disclose selection of a milk protein hydrolyzate. However, the examiner has made no such admission. Appellants have also argued that the specification teaches that "selecting the milk protein hydrolysate involves selecting the milk protein hydrolysate based on degree of hydrolysis". However, the claims do not require selecting one degree of hydrolysis

over another. The claims require selecting a degree of hydrolysis that is effective to increase protein concentration or rate of protein synthesis. The claims do not require choosing a degree of hydrolysis that provides a maximum level of protein synthesis, and the claims do not require choosing a degree of hydrolysis that provides a minimum level of protein synthesis; any level of protein synthesis sufficient, as long as it is "increased" relative to a reference point of the practitioners choosing.

The biochemist of ordinary skill would recognize that Smith teaches milk protein hydrolyzates which increase protein synthesis; by selecting the milk protein hydrolysates disclosed in the reference, the artisan of ordinary skill is meeting the requirements of the claims.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Qu, Zhensheng (*Journal of Nutrition* **126**(4) 906-912, 1996) in view of Stalker (USP 5,661,123).

Appellants have suggested that the examiner has "admitted" that Qu does not disclose selection of a milk protein hydrolyzate. However, the examiner has made no such admission. Appellants have also argued that the specification teaches that "selecting the milk protein hydrolysate involves selecting the milk protein hydrolysate based on degree of hydrolysis". However, the claims do not require choosing from among a series of degrees of hydrolysis, and selecting one and discarding the rest. The claims encompass the option of choosing a degree of hydrolysis that is the least effective at increasing

protein synthesis among the various possibilities. There is no requirement in the claims that the rate of protein synthesis be greater in any one organ than another, and the claims do not require that one choose a degree of hydrolysis which will produce such a relative rate of protein synthesis. All that is required is that the hydrolyzate provide some increase in protein synthesis, relative to some reference point, and which reference point is not specified in the claims.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) or Gray (USP 5,723,446) in view of Van Leeuwen (USP 6,001,878) or Gray (USP 5,723,446) in view of Panigrahi (USP 5,981,590).

Appellants have suggested that the examiner has "admitted" that Gray does not disclose selection of a milk protein hydrolyzate. However, the examiner has made no such admission. Appellants have also argued that the specification teaches that "selecting the milk protein hydrolysate involves selecting the milk protein hydrolysate based on degree of hydrolysis". However, the claims do not require selecting one degree of hydrolysis over another; all that is required is that the protein hydrolyzate have the property of causing some increase in protein synthesis, relative to a given reference point.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Boza, Julio (*Journal of Pediatric Gastroenterology and Nutrition* **22**(2) 186-193, 1996).

Appellants have suggested that the examiner has "admitted" that Boza does not disclose selection of a milk protein hydrolyzate. However, the examiner has made no such admission. Appellants have also argued that the specification teaches that "selecting the milk protein hydrolysate involves selecting the milk protein hydrolysate based on degree of hydrolysis". However, the claims do not require selecting one degree of hydrolysis over another; all that is required is that the protein hydrolyzate have the property of causing some increase in protein synthesis, relative to a given reference point.

. . . .

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/David Lukton/

Primary Examiner, Art Unit 1654

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654